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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,202	08/08/2005	Todd M Boyce	525400-344	4795
25763 7590 10/28/2008 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498				
EXAMINER SHAHRESTANI, NASTIR				
ART UNIT 3737		PAPER NUMBER		
MAIL DATE 10/28/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,202

Applicant(s)

BOYCE ET AL.

Examiner

NASIR SHAHRESTANI

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/08/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see REMARKS, filed 11/08/2007, with respect to the rejection(s) of claim(s) 1 and 14 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art reference(s).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-23 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (U.S. 4,436,684) in view of Janas et al. (U.S. 2001/0016353 A1).

White teaches a set of three dimensional coordinates defining a three dimensional representation of the selected internal structure is generated from the obtained representations and is employed to direct a sculpting tool to form a corporeal model of the selected structure. A model is formed from a work piece of suitable material by operating the machine-controlled sculpting tool device to control the trajectory of its cutting sculpting tool relative to the work piece in accordance with the coordinate data derived from the absorption coefficient representations of the structure obtained by the computerized x-ray tomographic device.

White discloses a method and the system where cutting plan is formulated from a computer based model; cut the bone manually or automated device; imaging step comprises scanning by computed tomography; or MRI, (See Fig. 1-5B).

As indicated by applicants REMARKS, White et al. do not specifically teach the imaging of donor bone as entered as a limitation to the claim language.

Janas et al. teach a process comprising: imaging a donor bone using scanning (par. 0041) and wherein following the imaging process, parameters are evaluated to assess the suitability of the bone for implantation. Within the broadest reasonable interpretation of the claim language, Janas et al. is applicable as prior art since there is no indication that imaging is done prior to implanting of the bone. However such a modification would have been obvious to one of ordinary skill in the art at the time of invention in order to eliminate the need for removing the bone after imaging as indicated by Janas et al., if the implant is not suited.

Regarding claims 2-13, it is inherent that a bone must be oriented in space before any action can take place onto said bone. Also, White discloses a method and the system where cutting plan is formulated from a computer based model; cut the bone manually or automated device; imaging step comprises scanning by computed tomography; or MRI, (See Fig. 1-5B).

Regarding claims 14, 30 and 31, and indicated before, in mathematics, extrapolation is the process of constructing new data points outside a discrete set of known data points and morphometrics (from the Greek: "morph," meaning shape or form, and "metron", meaning measurement) comprises methods of extracting measurements from shapes.

A model is formed from a workpiece of suitable material by operating the machine-controlled sculpting tool device to control the trajectory of its cutting sculpting tool relative to

the workpiece in accordance with the coordinate data derived from the absorption coefficient representations of the structure obtained by the computerized x-ray tomographic device.

Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchiyama et al. (NPL – “A Morphometric Comparison of Trabecular Structure of Human Ilium Between Microcomputed Tomography and Conventional Histomorphometry”) in view of Janas et al. (U.S. 2001/0016353 A1).

Uchiyama discloses: Recently, an imaging technique using microcomputed tomography (micro-CT) has emerged as a method for nondestructively assessing the microarchitecture of unprocessed surgical bone biopsy specimens. Using micro-CT, two-dimensional (2D) axial images were obtained from undecalcified transiliac bone biopsies which were taken from 15 patients with various metabolic bone diseases. Total area, bone area, and bone perimeter were determined, from which the bone volume (BV/TV), trabecular thickness (Tb.Th), trabecular number (Tb.N), and trabecular separation (Tb.Sp) were calculated semiautomatically and instantaneously. To evaluate the validity of this technique as a useful tool, the results were compared with those obtained from conventional histomorphometry. There were significant correlations between the two techniques for all parameters, with correlation coefficients ranging from 0.759 (Tb.N, $P = 0.005$) to 0.949 (BV/TV, $P = 0.0001$). Different resolutions seem to lead to major differences in perimeter values measured by the two methods. These factors may explain why the correlation coefficients of Tb.N and Tb.Th estimated from the perimeter and area is lower than that of BV/TV. Our results show that the micro-CT based on 2D images is a useful

tool for imaging and nondestructively quantifying the microarchitecture of trabecular bone in unprocessed surgical bone specimens.

Janas et al. teach a process comprising: imaging a donor bone using scanning (par. 0041) and wherein following the imaging process, parameters are evaluated to assess the suitability of the bone for implantation. Within the broadest reasonable interpretation of the claim language, Janas et al. is applicable as prior art since there is no indication that imaging is done prior to implanting of the bone. However such a modification would have been obvious to one of ordinary skill in the art at the time of invention in order to eliminate the need for removing the bone after imaging as indicated by Janas et al., if the implant is not suited.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NASIR SHAHRESTANI whose telephone number is (571)270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit
3737

/Nasir Shahrestani/
Examiner, Art Unit 3737